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Atty Dkt 1998002
Client No. 2302-1393
PATENT

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5/7/98 Patricia K. Jensen
Date Signature

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE 2900

In Re Application of:

BARCFIELD et al.

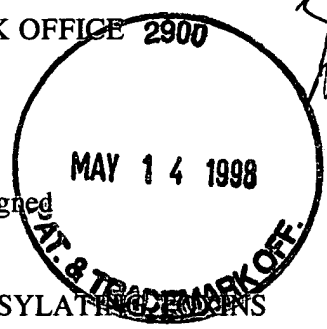
Serial No.: 09/044,696

Group Art Unit: Unassigned

Filing Date: March 18, 1998

Examiner: Unassigned

Title: DETOXIFIED MUTANTS OF BACTERIAL ADP-RIBOSYLATING PROTEINS
AS PARENTERAL ADJUVANTS



TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is an Information Disclosure Statement, including a Form PTO-1449 and copies of the cited references. It is believed that no fee is due.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: 5/7/98

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05/11/98
JCS87 U.S. PTO

Atty Dkt 1393.002
Client No. 2302-1393
PATENT

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Date

Patricia K. Simons
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

BARCHFELD et al.

Serial No.: 09/044,696

Group Art Unit: Unassigned

Filing Date: March 18, 1998

Examiner: Unassigned

Title: DETOXIFIED MUTANTS OF BACTERIAL ADP-RIBOSYLATING
TOXINS AS PARENTERAL ADJUVANTS

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

International Publication No. WO 92/19265, published November 12, 1992;

International Publication No. WO 93/13202, published July 8, 1993;

International Publication No. WO 95/17211, published June 29, 1995;

Agren et al., "Genetically Engineered Nontoxic Vaccine Adjuvant That Combines B Cell Targeting with Immunomodulation by Cholera Toxin A1 Subunit," *J. Immunol.* 158:3936-3946 (1997);

Akhiani et al., "Effect of Cholera Toxin on Vaccine-Induced Immunity and Infection in Murine Schistosomiasis Mansonii," *Infection and Immunity* 61(11):4919-4924 (1993);

Clements et al., "Adjuvant Activity of *Escherichia coli* Heat-Labile Enterotoxin and Effect on the Induction of Oral Tolerance in Mice to Unrelated Protein Antigens," *Vaccine* 6:269-277 (1988);

Elson, "Cholera Toxin as a Mucosal Adjuvant," *Mucosal Vaccines* Chapter 4:59-72 (1996);

Elson, "Cholera Toxin and its Subunits as Potential Oral Adjuvants," *Curr. Top. Microbiol. Immunol.* 146:29-33 (1989);

Elson et al., "A Lavage Technique Allowing Repeated Measurement of IgA Antibody in Mouse Intestinal Secretions," *Journal of Immunological Methods* 67:101-108 (1984);

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Lycke et al., "The Adjuvant Effect of *Vibrio Cholerae* and *Escherichia Coli* Heat-Labile Enterotoxins is Linked to Their ADP-Ribosyltransferase Activity," *Eur. J. Immunol.* 22:2277-2281 (1992);

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Nathaniel F. Pierce, "The Role of Antigen Form and Function in the Primary and Secondary Intestinal Immune Responses to Cholera Toxin and Toxoid in Rats," *J. Exp. Med.* 148:195-206 (1978);

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Tamura et al., "Effectiveness of Cholera Toxin B Subunit as an Adjuvant for Nasal Influenza Vaccination Despite Pre-Existing Immunity to CTB," *Vaccine* 7:503-505 (1989);

Van Der Heijden et al., "Manipulation of Intestinal Immune Responses Against Ovalbumin by Cholera Toxin and its B Subunit in Mice," *Immunology* 72:89-93 (1991);

Wilson et al., "Adjuvant Effect of Cholera Toxin on the Mucosal Immune Response to Soluble Proteins, Differences Between Mouse Strains and Protein Antigens," *Scand. J. Immunol.* 29:739-745 (1989); and

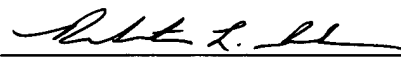
Wilson et al., "Adjuvant Action of Cholera Toxin and Pertussis Toxin in the Induction of IgA Antibody Response to Orally Administered Antigen," *Vaccine* 11(2):113-115 (1993).

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are

accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 5/7/98

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